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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,458	11/21/2001	J. G. J. Egberink	2000.602 US	5578
31846	7590	11/24/2003	EXAMINER	
INTERVET INC 405 STATE STREET PO BOX 318 MILLSBORO, DE 19966			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,458	EGBERINK ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following are received:

- a) Application filed 11/21/01 for which a filing date of 11/21/01 was not granted
- b) Request for corrected filing receipt filed 04/08/02
- c) Specification, claims and abstract filed 04/08/02 for which a filing date of 04/08/02 was granted
- d) Response to Notification of Missing Parts
- e) Declaration filed 04/08/02
- f) Declaration under 37 C.F.R. 5.25 filed 05/28/02
- g) Statement filed 06/14/02
- h) Supplemental declaration filed under 37 C.F.R. 55.25 #3
- i) Response to Decision on Request under 37 C.F.R. 5.25
- j) Change of Address filed 11/18/02

There are two sets of claims in the application, but it is noted that the effective filing date is 04/08/02 and thus the specification, claims and abstract filed on 04/08/02 are examined.

Specifically the claims filed on 04/08/02 are examined.

Suggestion:

If the claims filed on 04/08/02 are not the set of claims applicants intend for examination, applicants may amend the claims to reflect that which applicants intend for examination. It is further noted that the claims filed on 11/21/01 appear to be in better form in terms of the format. The subject matter in both sets of claims is the same.

Claims 1-4 are pending.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 has cited the references, they have not been considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "cellulosic" and the term "cellulosic" confers the element of cellulose-type polymer to the claims and the claim is indefinite because it is not immediately clear what cellulose is included or excluded from the term. See *Ex parte Copenhaver*, POBA, 1955, 109 USPQ 118-119.

It is suggested that claim 1 recite ---cellulose--- in place of "cellulosic"

3. Claim 1 recites the limitation "the amount of carbohydrate binder" in line 6. There is insufficient antecedent basis for this limitation in the claim because the claim made no previous mention of "carbohydrate binder". It appears that carbohydrate binder is microcrystalline cellulose (see page 3, lines 19-23 of instant specification). Thus, it is respectfully suggested that

claim 1 recite ---microcrystalline cellulose--- in place of “carbohydrate binder” since microcrystalline cellulose is previously recited in line 4.

Claim 1 contains the trademark/trade name AVICEL. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe specific microcrystalline cellulose and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over David et al. (US 5,478,572) in view of Dennis et al. (US 5,169,638).

David discloses gepirone containing extended release formulations (abstract). David's composition is administered orally as a once a day extended release formulation containing gepirone hydrochloride, cellulose polymer matrix and suitable amounts of pharmaceutical

excipient (column 1, lines 46-55). A specific composition contains about 0.6 to about 10.7% gepirone hydrochloride, about 72.7 to about 82.1% hydroxypropylmethylcellulose having a viscosity of 15,000 to about 100,000 cps, about 0 to about 0.3% iron oxide, about 11.0 to about 16.7% microcrystalline cellulose, about 0.42 to about 0.47% colloidal silica and about 0.3 to about 1.0% magnesium stearate (column 2, lines 30-40). David further discloses a composition that would generally contain about 0.5% to about 12.0% of active pharmaceutical agents, from about 99.5 to about 88.0% combination of sustaining agents (column 3, line 34 to column 4, line 1), which is a polymeric cellulose matrix (column 4, lines 2-8); and preferred compositions contain gepirone hydrochloride and are administered as tablets (column 4, lines 12-15). In general, the composition of David is formulated as tablets, capsules, caplets, lozenges, powders, suspension and syrups (column 3, lines 9-13). Gepirone is used as an antidepressant and anxiolytic and is typically used to treat depression, dysthymia, impulse disorders, panic attacks (column 1, lines 11-13) and David orally administers the composition to deliver an effective anxiolytic amount of gepirone to a mammal and specifically to a human patient (column 3, lines 1-4). See also claims 1-16.

Dennis discloses buoyant controlled release pharmaceutical powder formulation (abstract). Gepirone is one of the drugs disclosed that can be used in the composition of Dennis (column 4, line 21-24 and 35) and a typical formulation comprises sodium alginate, hydroxypropylmethylcellulose (METHOCEL E4M), AVICEL pH 101 (microcrystalline cellulose, lactose, hydroxypropylmethylcellulose (binder Methocel E5) and magnesium stearate lubricant (example 1) and in this example 1, Verapamil is used to exemplify the drugs listed in column 4, lines 21-61).

David teaches the composition and method of the instant claims except that David does not use the specific microcrystalline cellulose of AVICEL pH 101. Regarding the maximum amount of gepirone hydrochloride of 12.0% in David versus the minimum amount of 13% of the instant claim, applicants have no showing regarding what happens at a low amount of 13% or 12%. Regarding AVICEL pH 101, Dennis discloses a composition of gepirone and AVICEL pH 101 and Dennis is thus relied upon for a teaching of gepirone and AVICEL. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a composition containing gepirone hydrochloride and orally administer the formulation to a human subject in need thereof to treat central nervous system disorders according to the teaching of David. One having ordinary skill in the art would have been motivated to substitute one microcrystalline cellulose with another such as AVICEL pH 101 with the expectation that AVICEL pH 101 would hold the composition together so that minimal loss from the composition occurs during production and handling.

6. Suggestion: The use of the trademark has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.


Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

7. specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.


Blessing Fubara
Patent Examiner
Tech. Center 1600